Clinical Review & Education

**Special Communication**

World Medical Association Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects

World Medical Association

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the: 29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983 41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 52nd WMA General Assembly, Edinburgh, Scotland, October 2000

53rd WMA General Assembly, Washington, DC, USA, October 2002 (Note of Clarification added) 55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)

59th WMA General Assembly, Seoul, Republic of Korea, October 2008 64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Dec- laration of Helsinki as a statement of ethical principles for medi- cal research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consider- ation of all other relevant paragraphs.

1. Consistent with the mandate of the WMA, the Declaration is ad- dressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

1. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consider- ation,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when provid- ing medical care.”
2. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and con- science are dedicated to the fulfilment of this duty.
3. Medical progress is based on research that ultimately must in- clude studies involving human subjects.
4. The primary purpose of medical research involving human sub- jects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic in- terventions (methods, procedures and treatments). Even the

best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

1. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.
2. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
3. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self- determination, privacy, and confidentiality of personal informa- tion of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.
4. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and stan- dards. No national or international ethical, legal or regulatory re- quirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
5. Medical research should be conducted in a manner that mini- mises possible harm to the environment.
6. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific edu- cation, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care profes- sional.

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